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**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

| | |
|---|---|
| **JAZZ PHARMACEUTICALS, INC.,**<br><br>**Plaintiff,**<br><br>**vs.**<br><br>**ROXANE LABORATORIES, INC.,**<br><br>**Defendant.** | **C.A. No. 2:12-cv-06761 (ES) (CLW)** |

**ROXANE LABORATORIES, INC.'S ANSWER,**
**AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT**

Defendant, Roxane Laboratories, Inc. ("Roxane"), for its Answer, Affirmative Defenses and Counterclaims to Plaintiff Jazz Pharmaceuticals, Inc.'s ("Jazz Pharmaceuticals") Complaint for Patent Infringement ("the Complaint"), states as follows:

**Nature of the Action**

1. Roxane admits that the Complaint purports to be a civil action for patent infringement. Roxane also admits that it filed an Abbreviated New Drug Application ("ANDA") No. 202090 with the United States Food and Drug Administration ("FDA"), seeking approval to commercially market a generic version of Jazz Pharmaceuticals' XYREM® drug product prior to

the expiration of United States Patent No. 8,263,650 ("the '650 patent"). Roxane denies all other allegations contained in paragraph 1 of the Complaint.

**The Parties**

2. Roxane admits on information and belief that Jazz Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3180 Porter Drive, Palo Alto, California 94304. Roxane denies all other allegations contained in paragraph 2 of the Complaint.

3. Roxane admits the allegations contained in paragraph 3 of the Complaint.

4. Roxane admits that it is registered to do business in the State of New Jersey and maintains a registered agent for service of process in New Jersey. Roxane further admits that it sells generic drug products throughout the United States, including this judicial district. Roxane further admits that it has litigated patent cases in this district and that, in at least some of those actions, Roxane has asserted counterclaims. Roxane denies all other allegations contained in paragraph 4 of the Complaint.

**Jurisdiction and Venue**

5. Roxane admits the allegations contained in paragraph 5 of the Complaint.

6. For purposes of this action, Roxane consents to this Court's jurisdiction. Roxane denies all other allegations contained in paragraph 6 of the Complaint.

7. For purposes of this action, Roxane consents that venue is proper in this district. Roxane denies all other allegations contained in paragraph 7 of the Complaint.

**The Patents in Suit**

8. Roxane admits that what purports to be a copy of the '650 patent is attached to the Complaint as Exhibit A. Roxane further admits that Exhibit A (a) is entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy,"

and (b) lists Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan as "Inventors." Roxane denies all other allegations contained in paragraph 8 of the Complaint.

**The XYREM® Drug Product**

9. Roxane admits that New Drug Application ("NDA") No. 21-196 was approved by the FDA and that Jazz Pharmaceuticals is listed as the applicant for that NDA. Roxane denies all other allegations contained in paragraph 9 of the Complaint.

10. Roxane admits that the '650 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to XYREM®. Roxane denies all other allegations contained in paragraph 10 of the Complaint.

**Acts Giving Rise to this Suit**

11. Roxane admits that it filed ANDA No. 202090. Roxane's ANDA speaks for itself as to its contents. Roxane denies all other allegations contained in paragraph 11 of the Complaint.

12. Roxane admits that it provided a written certification to the FDA pursuant to Section 505 of the Federal Food Drug and Cosmetics Act ("FFDCA"). Roxane's certification speaks for itself as to its contents. Roxane denies all other allegations contained in paragraph 12 of the Complaint.

13. Roxane admits that by letter dated October 5, 2012 ("Roxane's Notice Letter"), Roxane notified Jazz Pharmaceuticals of its ANDA certification that the claims of the '650 patent are invalid, unenforceable, and/or will not be infringed by Roxane. Roxane's ANDA speaks for itself as to its contents. Roxane further admits that in Roxane's Notice Letter, Roxane informed Jazz Pharmaceuticals that Roxane seeks FDA approval for Roxane's sodium oxybate oral solution. Roxane denies all other allegations contained in paragraph 13 of the Complaint.

**Count I: Infringement of the '650 Patent**

14. Roxane repeats, reasserts and incorporates by reference its answers to paragraphs 1-13 of the Complaint above, as if fully set forth herein.

15. Roxane denies the allegations contained in paragraph 15 of the Complaint.

16. Roxane admits the allegations contained in paragraph 16 of the Complaint.

17. Roxane denies the allegations contained in paragraph 17 of the Complaint.

18. Roxane denies the allegations contained in paragraph 18 of the Complaint.

19. Roxane denies the allegations contained in paragraph 19 of the Complaint.

20. Roxane denies the allegations contained in paragraph 20 of the Complaint.

21. Roxane denies the allegations contained in paragraph 21 of the Complaint.

22. Roxane denies the allegations contained in paragraph 22 of the Complaint.

**PRAYER FOR RELIEF**

Roxane specifically denies that Jazz Pharmaceuticals is entitled to the general or specific relief requested against Roxane, or to any relief whatsoever, and prays for judgment in favor of Roxane dismissing this action with prejudice, and awarding Roxane its reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

**AFFIRMATIVE DEFENSES**

Without prejudice to the denials set forth in its Answer and without admitting any allegations of the Complaint not otherwise admitted, Roxane avers and asserts the following Affirmative Defenses to the Complaint of Plaintiff Jazz Pharmaceuticals.

**FIRST AFFIRMATIVE DEFENSE**
**(Noninfringement of U.S. Patent No. 8,263,650)**

The manufacture, use, sale, offer to sell or importation into the United States of Roxane's proposed sodium oxybate oral solution product that is the subject matter of ANDA No. 202090 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,263,650 ("the '650 patent") either literally or under the doctrine of equivalents.

**SECOND AFFIRMATIVE DEFENSE**
**(Invalidity of U.S. Patent No. 8,263,650)**

Upon information and belief, the claims of the '650 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to §§ 101, 102, 103 and/or 112.

**THIRD AFFIRMATIVE DEFENSE**
**(Inequitable Conduct)**

Upon information and belief, the claims of the '650 patent are unenforceable because of Jazz Pharmaceutical's inequitable conduct, as alleged more specifically in Roxane's Counterclaim set forth below.

**FOURTH AFFIRMATIVE DEFENSE**
**(Patent Misuse)**

Upon information and belief, the claims of the '650 patent are unenforceable due to Jazz Pharmaceutical's inequitable conduct committed during its prosecution with unclean hands including, without limitation, the failure of the applicants, inventors, and/or those involved in the prosecution, with the intent to deceive the United States Patent and Trademark Office, to disclose prior art that was material to the examination of the '650 patent, as alleged more specifically in Roxane's Counterclaims set forth below.

## COUNTERCLAIM

1. Counterclaimant Roxane Laboratories, Inc. ("Roxane") is a corporation organized under the laws of Nevada having a principal place of business at 1809 Wilson Road, Columbus, Ohio 43228-8601.

2. Upon information and belief, Plaintiff and Counterclaim Defendant Jazz Pharmaceuticals Inc. ("Jazz Pharmaceuticals") is a corporation organized under the laws of Delaware having a principal place of business at 3180 Porter Drive, Palo Alto, California 94304.

3. As a consequence of Jazz Pharmaceuticals' Complaint against Roxane, there is now an existing, continuing actual controversy between Jazz Pharmaceuticals and Roxane regarding the alleged infringement, validity and enforceability of U.S. Patent No. 8,263,650 ("the '650 patent").

4. This Court has jurisdiction over the subject matter of these counterclaims pursuant to §§ 1331 and 1338(a) of Title 28 of the U.S. Code, as they involve substantial claims arising out of the United States Patent Act, 35 U.S.C. § 1, et. seq.

5. This Court may declare the rights and legal relations for the parties pursuant to §§ 2201 and 2202 of Title 28 of the U.S. Code and § 271(e)(5) of Title 35 of the U.S. Code because Roxane's Counterclaims present an actual controversy within the Court's jurisdiction that the patent asserted by Jazz Pharmaceuticals against Roxane are not infringed and/or are invalid.

6. Venue for these Counterclaims is proper within this District in which Jazz Pharmaceuticals' Complaint is pending.

### COUNT 1
### Declaratory Judgment of Noninfringement of the '650 Patent

7. The manufacture, use, sale, offer to sell or importation into the United States of Roxane's proposed sodium oxybate oral solution product that is the subject matter of ANDA No.

202090 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of the '650 patent either literally or under the doctrine of equivalents.

**COUNT 2**
**Declaratory Judgment of Invalidity of the '650 Patent**

8. Upon information and belief, the claims of the '650 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to §§ 101, 102, 103 and/or 112.

**COUNT 3**
**Declaratory Judgment of Unenforceability of the '650 Patent**

9. Counterclaimant Roxane incorporates paragraphs 1-8 of its Counterclaim by reference, as though fully set forth herein.

10. The '650 patent and its claims are unenforceable due to inequitable conduct committed during the prosecution, as set forth more fully below.

11. Title 37 of the Code of Federal Regulations §1.56 and the Manual for Patent Examining Procedure §2000.01 et seq. impose a duty of candor and good faith on each individual associated with the filing and prosecution of a patent application before the United States Patent and Trademark Office ("USPTO"), which requires that he or she disclose to the USPTO all information that is material to the patentability of the application under examination. Breach of this duty of candor, good faith and honesty with an intent to deceive the USPTO constitutes inequitable conduct so as to render at least the affected patent unenforceable.

12. Upon information and belief, the '650 patent is void, unenforceable and of no legal effect by reason of inequitable conduct on the part of the inventors thereof and/or those acting on their behalf before the USPTO. Jazz Pharmaceuticals, the inventors and/or those acting on their behalf committed acts of inequitable conduct by failing to disclose information

material to the prosecution of the application. Specifically, Jazz Pharmaceuticals, the inventors, and/or those acting on their behalf withheld material invalidating prior art from the USPTO. Such acts were committed with an intent to deceive the USPTO.

13. The '650 patent is entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt For the Treatment of Narcolepsy" and issued from Application Serial No. 13/446,940, which Jazz filed with the USPTO on April 13, 2012.

14. Claim 1 of the '650 patent claims "[a] pharmaceutical composition, comprising an aqueous solution of about 500 mg/ml sodium gamma-hydroxybutyrate, wherein the composition has a pH of about 7.3 to about 8.5, wherein the composition is chemically stable and resistant to microbial growth, and wherein the composition is free of preservatives."

15. The '650 patent issued from an application which is a continuation of U.S. Application No. 12/913,644, which is a continuation of the application which issued as U.S. Patent No. 7,851,506 ("the '506 patent"), which is a divisional of the application which issued as U.S. Patent No. 7,262,219 ("the '219 patent"), which is a divisional of the application which issued as U.S. Patent No. 6,780,889 ("the '889 patent"), which is a divisional of the application which issued as U.S. Patent No. 6,472,431 ("the '431 patent").

16. The validity and enforceability of the claims of the '431, '889, '219 and '506 patents (collectively, "the '431 patent family") are already at issue in Civil Action No. 10-cv-6108 currently pending in this Court.

17. The '650 patent and the other individual patents of the '431 patent family each identifies the same individuals as inventors. The named inventors are as follows: Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad, and Dayton Reardan.

18. All of the named inventors of the '650 patent and the other patents in the '431 patent family signed a declaration under oath stating that:

> I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with 37 C.F.R. §1.56 (attached hereto). I also acknowledge my duty to disclose all information known to be material to patentability which became available between a filing date of a prior application and the national PCT international filing date in the event this is a Continuation-in-Part application in accordance with 37 C.F.R. §1.63(e).

19. The applications that matured into the '650, '431, '889, '219 and '506 patents were all prosecuted by attorneys and/or patent agents, including Ms. Monique M. Perdok Shonka from the law firm of Schwegman, Lundberg & Woessner, P.A.

20. Under 37 C.F.R. §1.56, patent attorneys prosecuting patent applications are individuals subject to the duty of candor and good faith in dealing with the USPTO, which includes a duty to disclose to the USPTO all information known to those individuals to be material to patentability.

21. Upon information and belief, during the prosecution of the '650 patent, Jazz Pharmaceuticals, the inventors and/or those acting on their behalf associated with the preparation, filing and/or prosecution of the application that matured into the '650 patent, such as the attorneys and/or patent agents from the law firm of Schwegman, Lundberg & Woessner, P.A., including Ms. Perdok Shonka, were each aware of his or her duty to disclose information material to patentability to the USPTO.

22. Upon information and belief, Jazz Pharmaceuticals, the inventors and/or those acting on their behalf associated with the preparation, filing and/or prosecution of the application that matured into the '650 patent, including Ms. Perdok Shonka, failed to disclose Chem

Abstract ES302338 ("CA 338"), a non-cumulative prior art reference material to the patentability of the claims of the '650 patent, to the USPTO during prosecution of that application.

23. CA 338 sets forth information contained in Spanish Patent No. ES 302338, entitled "Solutions of 4-hydroxybutyric acid salts for injection," issued on January 16, 1965, from application number ES 1964-30233864 filed on July 22, 1964.

24. CA 338 teaches the preparation of chemically stable, microbial growth resistant, preservative free, pH 7.2-7.7 solutions of the sodium salt of gamma-hydroxybutyrate by reacting pure sodium hydroxide (NaOH) with gamma-butyrolactone (GBL) so as not to prepare solutions that "have far too high a pH for injection." CA 338, therefore, would have been material to claim 1 in the application that matured into the '650 patent, alone or in combination with other references. Furthermore, CA 338 is not cumulative of any reference that was already in front of the USPTO.

25. On April 14, 2011, over a year before the application that matured into the '650 patent was filed, Roxane provided to Jazz Pharmaceuticals its Initial Invalidity Contentions regarding the '431 patent family in Civil Action No. 10-cv-6108, as required by the Local Patent Rules of this Court. Roxane contended in its Initial Invalidity Contentions that one or more of the claims of the '431 patent are invalid in light of CA 338 in combination with other references.

26. Roxane provided its Initial Invalidity Contentions with respect to the '431 patent, as well as the other patents-in-suit, to Jazz Pharmaceuticals on a non-confidential basis. Upon information and belief, these Initial Invalidity Contentions were provided by Jazz Pharmaceuticals, or those acting on its behalf, to attorneys and/or patent agents from the law firm of Schwegman, Lundberg & Woessner, P.A., including Ms. Perdok Shonka, who have

subsequently filed copies of the Initial Invalidity Contentions during prosecution of related patent applications, such as U.S. Patent Application No. 13/453,915.

27. Upon information and belief, as of at least April 14, 2011, Jazz Pharmaceuticals, the inventors and/or those acting on their behalf associated with the preparation, filing and/or prosecution of the application that matured into the '650 patent were aware of CA 338.

28. Specifically, CA 338 was known to Ms. Perdok Shonka, who disclosed CA 338 to the USPTO in an Information Disclosure Statement during the prosecution of a co-pending, related Application Serial No. 13/446,892 ("the '892 application"), which also claims priority to the '431 patent and was co-pending at the same time as the application for the '650 patent. The '892 application, instead of claiming the pH of sodium oxybate liquid formulation, claims a method of orally dosing a liquid formulation of sodium oxybate with no mention of formulation specifics or pH.

29. Upon information and belief, Jazz Pharmaceuticals, the inventors or those acting on their behalf associated with the preparation, filing and/or prosecution of the application that matured into the '650 patent, including Ms. Perdok Shonka, knew that CA 338 was material to the patentability of at least claim 1 of the '650 patent and not cumulative of any prior art that is already in front of the USPTO.

30. Jazz Pharmaceuticals, the inventors or those acting on their behalf associated with the preparation, filing and/or prosecution of the application that matured into the '650 patent, including Ms. Perdok Shonka, did not disclose CA 338 to the USPTO during the pendency of the application that matured into the '650 patent.

31. Failure to disclose CA 338 to the USPTO was an omission by Jazz Pharmaceuticals, the inventors or those acting on their behalf associated with the preparation,

filing and/or prosecution of the application that matured into the '650 patent, including Ms. Perdok Shonka, in contravention of their duties to the USPTO during the prosecution of the '650 patent.

32. Upon information and belief, Jazz Pharmaceuticals, the inventors or those acting on their behalf associated with the preparation, filing and/or prosecution of the application that matured into the '650 patent, including Ms. Perdok Shonka, had knowledge of, and intentionally withheld, CA 338 from the USPTO with intent to deceive the USPTO.

33. This omission was material to patentability because, among other things, CA 338 was relevant to the question of whether the claims of the '650 patent would have been novel or obvious to one of ordinary skill in the art and because there is a substantial likelihood that a reasonable examiner would have considered CA 338 important in deciding whether to allow at least claim 1 of the '650 patent because this reference either alone or in combination with other art, teaches or implies elements of, or renders obvious, at least claim 1 of the '650 patent.

34. CA 338 was not cumulative of any prior art that was already before the examiners who examined the '431 patent family or the application for the '650 patent.

35. Jazz Pharmaceuticals, the inventors or those acting on their behalf associated with the preparation, filing and/or prosecution of the application that matured into the '650 patent, including on information and belief Ms. Perdok Shonka, believed the CA 338 reference was sufficiently relevant to this family of patent applications and not cumulative of any prior art already in front of the USPTO to cite CA 338 to the USPTO during the prosecution of the '892 application. CA 338 has less direct relevance to the '892 application claims, which relate to a dosing schedule, than to the '650 patent claims, which relate to liquid formulation pH.

36. Citation of CA 338 during the prosecution of the less relevant '892 application but not the more relevant '650 patent evidences an intent to deceive the USPTO into granting the '650 patent by Jazz Pharmaceuticals, the inventors or those acting on their behalf associated with the preparation, filing and/or prosecution of the application that matured into the '650 patent, including, on information and belief Ms. Perdok Shonka.

37. But for the material omission of Jazz Pharmaceuticals, the inventors or those acting on their behalf associated with the preparation, filing and/or prosecution of the application that matured into the '650 patent, including Ms. Perdok Shonka, the USPTO would not have issued at least claim 1 of the '650 patent.

38. By failing to cite CA 338 during prosecution of the '650 patent, Jazz Pharmaceuticals, the inventors or those acting on their behalf associated with the preparation, filing and/or prosecution of the application that matured into the '650 patent, including Ms. Perdok Shonka, materially misrepresented the patentability of at least claim 1 of the '650 patent.

39. On information and belief, this material misrepresentation was part of a deliberately planned and carefully executed scheme carried out by Jazz Pharmaceuticals, the inventors or those acting on their behalf associated with the preparation, filing and/or prosecution of the application that matured into the '650 patent, including Ms. Perdok Shonka, to defraud the USPTO and the courts and effect issuance of at least claim 1 of the '650 patent.

40. This material omission of Jazz Pharmaceuticals, the inventors or those acting on their behalf associated with the preparation, filing and/or prosecution of the application that matured into the '650 patent, including Ms. Perdok Shonka, amounted to affirmative egregious misconduct in dealing with the USPTO.

41. For each of the aforesaid reasons, Roxane is entitled to a declaratory judgment that the '650 patent is unenforceable due to inequitable conduct.

**ROXANE'S PRAYER FOR RELIEF**

WHEREFORE, Roxane respectfully requests that the Court enter judgment against Jazz Pharmaceuticals as follows:

(A) Declaring that Roxane would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,263,650 either literally or under the doctrine of equivalents by submitting ANDA No. 202090;

(B) Declaring that Roxane's proposed sodium oxybate oral solution that is the subject of ANDA No. 202090 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of U.S. Patent No. 8,263,650 either literally or under the doctrine of equivalents;

(C) Declaring that U.S. Patent No. 8,263,650 is invalid for failure to comply with one or more provisions of 35 U.S.C. § 101, 102, 103, and/or 112;

(D) Declaring that U.S. Patent No. 8,263,650 is unenforceable due to inequitable conduct;

(E) Granting an injunction permanently preventing Jazz Pharmaceuticals from asserting or enforcing U.S. Patent No. 8,263,650 against Roxane, its divisions, subsidiaries, licensees, customers or agents;

(F) Awarding Roxane its reasonable costs and attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285;

(G) Such further and other relief as this Court may deem just and proper.

Dated: November 9, 2012

Respectfully Submitted,

s/ THEODORA MCCORMICK
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**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

Pursuant to L. Civ. R. 11.2, I hereby certify that to the best of my knowledge, information, and belief, aside from this action, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: November 9, 2012

s/ THEODORA MCCORMICK
Theodora McCormick

**CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1(D)(1)**

I hereby certify that this action does not fall within the requirement for compulsory arbitration set forth in Local Civil Rule 201(d)(1) because the relief sought consists of non-monetary relief (i.e., permanent injunction).

Dated: November 9, 2012

s/ THEODORA MCCORMICK
Theodora McCormick

**CERTIFICATE OF SERVICE**

I hereby certify that, on November 9, 2012, I electronically filed the attached Answer, Affirmative Defenses and Counterclaims to Plaintiff's Complaint with the clerk of the Court by using the Court's CM/ECF system, and accordingly served all parties who receive notice of the filing via the Court's CM/ECF system.

s/ THEODORA MCCORMICK
Theodora McCormick